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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/247,406	02/10/99	CAPLAN M	HS105

HM22/0626

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EXAMINER	
WESSENDORF, T	
ART UNIT	**PAPER NUMBER**
1627	
DATE MAILED:	06/26/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/247,406	Caplan
Examiner	**Group Art Unit**
T. Wessendorf	1627

☒ Responsive to communication(s) filed on Mar 23, ~~1900~~ 2000

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) 1-88 is/are pending in the applicat

Of the above, claim(s) 18, 24-45, and 54-88 is/are withdrawn from consideration

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-17, 19-23, and 46-53 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 2

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Applicant's election with traverse of Group I, claims 1-28 (immunostimulator) in Paper No. 4 is acknowledged. The traversal is on the ground(s) that Groups I, VII, IX and X are substantially the same as each involves the same basic steps and processes. This is not found persuasive because the process of Group I and Groups VII, IX-X have different functions and effects as per MPEP 806.04 cited by applicant. While the method steps recite broadly the same process steps for each of these groups however, it is apparent from these claims that the process to identify a component from Group I would not be the same as the process of identifying the components present in Groups VII and IX-X. For example, the identification of a fusion protein would not identify a non-fusion protein. A prior art reference anticipating a process step for one component would not render obvious that of the other components. Furthermore, the search would be burdensome since different species are required in the process steps. The prior art Patent search is not co-extensive with literature searches. Thus, to search for the different species involve in the process steps would entail undue burden. Applicants have not tended any evidence to show that the process steps for one species would render obvious other species.

However, upon reconsideration of the restriction requirements and applicants' arguments, Group VII, claims 46-53 would be examined with Group I, claims 1-28.

Claims 18, 24-45, 54-88 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species and inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 5. Claims 1-17, 19-23 and 46-53 are under consideration.

The requirement is still deemed proper and is therefore made FINAL.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-17, 19-23 and 46-53 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A). The recited method is indefinite as to whether a method of making or using is being claimed. E.g., claim 1. The recited "monospecific" within the claimed context, as used in the alternative reaction with an individual and fragments of antibodies is indefinite. Furthermore, the terms "desired characteristic" and " polypeptide of interest", within the claimed context, are relative terms and the standard or basis by which said terms are measured is not clear.

B). There is no antecedent basis of support for the recited "the undesirable immune response" in claim 5. Furthermore, the recited "the undesirable immune response is mediated by the antibody reaction" and "wherein the antibody reactivity is involved in the undesirable immune response" are redundant as these statements mean the same thing except worded differently. If the

undesirable immune response is mediated by an antibody, it follows that the antibody is involved in the undesirable immune response. It is not clear, within the claimed context, the difference between the antibody being associated or involved in the undesirable immune response, especially in the absence of positive showing in the specification.

Claims 22-23 are indefinite and appear to broaden the base claim as these claims improperly recite a method of use of the polypeptide obtained by what appears to be a process of making of the polypeptide as recited in the base claim.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1-6, 8, 9, 11-14, 16-17, 19, 21, 46-49 and 52-53 are rejected under 35 U.S.C. 102(a) as being anticipated by Hakkaart et al (Allergy).

Hakkart disclose at e.g., page 166, col. 1, "Materials and Methods" up to page 170, col. 1 and page 171, col. 1 a method comprising of mutanizing the house-dust-mite allergen, Der p 2 by replacing the Cys residues with Ala by the method of cDNa that generates a collection of fragments of Der p2 mutants and then identifying the fragments that are monospecific to the mab produced from immunization of mice wherein the characteristic of the mutants still possessed the ability to induce histamine release from basophilic leukocytes. The specific process steps of Hakkaart utilizing the specific allergen in the process steps to identify those mutants that

immunoreact with antibodies fully meets the instant broad process steps for any kind of protein mutations.

Claims 1-6, 8,-9, 11-14, 16-17, 19, 21-23, 46-49 and 52-53 are rejected under 35 U.S.C. 102(b) as being anticipated Smith (J. Allergy and Clin. Immuno.).

Smith discloses a method comprising of mutanizing the house-dust-mite allergen, Der p 2 by deleting e.g., the Cys 73-38 bond residues with Ala by the method of cDNa that generates a collection of fragments of Der p2 mutants and then identifying the fragments that are monospecific to the mab produced from immunization of mice wherein the characteristic of the mutants still possessed the ability to induce histamine release from basophilic leukocytes. The specific process steps of Smith utilizing the specific allergen in the process steps to identify those mutants that immunoreact with antibodies fully meets the instant broad process steps for any kind of protein mutations. See the entire abstract.

Claims 1-3, 6 are rejected under 35 U.S.C. 102(b) as being anticipated by Jespers et al (The. Jrnl, Mol. Biol.).

The broadly recited method comprising providing a collection of mutant polypeptide wherein the amino acid sequence of each mutant polypeptide differs in at least one position from a polypeptide of interest, and identifying the mutant polypeptide within the collection that have an alteration in antibody reactivity compared to the polypeptide of interest and retain at least one desired characteristic, wherein alteration in the antibody reactivity is determined by exposing he mutant polypeptide to individual antibodies or antibody fragments that are monospecific for the

polypeptide of interest is fully met by the process step of Jespers at e.g., page 704. Jespers disclose a method wherein a library of randomized antigen variants containing most single, double and triple amino acid mutants generated by single nucleotide substitutions is produced by error-prone PCR amplification of the DNA sequence encoding the protein antigen. The phage - displayed library is then selected fro epitope mutants by passing through an affinity matrix derivatized with a specific antibody and positively selected for retention of function.

Claims 6, 7 and 50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hakkaart et al in view of Steinberger et al (The Jrnl. of Biol.Chemistry).

Hakkaart is discussed above. Hakkaart does not expressly recites that the antibodies are from combinatorial antibodies .Steinberger discloses antibodies derived from combinatorial library that reacts with allergens and disclose that said combinatorial library facilitate studies on the molecular interaction between IgE antibodies and allergens and encourages the consideration of specific IgE fabs that are capable of interfering with allergen-IgE binding as potential therapeutic tools. See e.g., page 10967 col. 1 . Accordingly, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use a combinatorial IgE in the method of Hakkaart for the advantage derived in the use of said combinatorial library as taught by Steinberger, above.

Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hakkaart et al in view of Espanion (DTW).

Hakkaart does not disclose expressing the polypeptide in transgenic animal. Espanion disclose that potential applications of gene transfer in farm animals are increased of disease resistance and that transgenic animal could be an attractive alternative for conventional production methods. See e.g., the Summary section at page 320. It would have been obvious to one having ordinary skill in the art to use transgenic animals for the expression of peptide for the advantage derived in the use of said transgenic methods over the conventional production methods of peptides.

No claim is allowed.

The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1627.

Certain papers related to this application may be submitted to Art Unit 1627 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 O.G. 61 (November 16, 1993) and 1157 O.G. 94 (December 28, 1993)(see 37 C.F.R. 1.6(d)). The official fax telephone numbers of the Group are (703)308-7924. NOTE: If applicant does submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO

DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to T. Wessendorf whose telephone number is (703) 308-3967. The examiner can normally be reached on Mon. to Fri. from 8 to 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jyothsna Venkat Ph.D., can be reached on (703) 308-0570.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

T. Wessendorf

6/19/00

T. Wessendorf
Patent Examiner
Art Unit 1627